1642.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

ARATHOON ET AL.

Examiner:

A. HOLLERAN

Serial No.:

09/373,403

Group Art Unit:

1642

Filed:

AUGUST 12, 1999

Docket:

A METHOD FOR MAKING MULTISPECIFIC ANTIBODIES HAVING

11669.133USC1

Confirmation No.:

2534

23552

Title:

Customer No.:

HETEROMULTIMERIC AND COMMON COMPONENTS

**CERTIFICATE UNDER 37 CFR 1.8:** 

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

on October 1, 2003.

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

We are transmitting herewith the attached:

Transmittal Sheet in duplicate containing Certificate of Mailing

Supplemental Information Disclosure Statement, Form 1449, 27 References

Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

MERCHANT & GOULD P.C. P.O. Box 2903, Minneapolis, MN 55402-0903 612.332.5300

Name: Katherine M. Kowalchyk

Reg. No.: 36,848 KKowalchyk:sab

**PATENT** 

IN THE LIMITED STATES PATENT AND TRADEMARK OFFICE

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S/N 09/373,4

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on October 1, 2003.

Name: Sheryl A. Boerboom

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(c))

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing of a first Office Action after the filing of a Request for Continued Examination under 37 C.F.R. § 1.114 or a CPA under 37 C.F.R. § 1.53(d). Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

The Examiner's attention is directed to co-pending applications U.S. Serial No. 09/520,130 filed March 7, 2000, U.S. Serial No. 09/863,693 filed May 23, 2001, and U.S. Serial No. 10/143,437 filed May 10, 2002.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a

reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903 Minneapolis, Minnesota 55402-0903

(612) 332-5300

Date: Oct. 1, 2003

Katherine M. Kowalchyk
Reg. No. 36 840

Reg. No. 36,848

KMK:sab

| FORM 1449* INFORMATION DISCLOSURE STATEMENT    | Docket Number:<br>11669.133USC1 | Application Number: 09/373,403 |  |
|--|---------------------------------|--------------------------------|--|
| IN AN APPLICATION                              | Applicant: ARATHOON ET AL.      |                                |  |
| OCT 0 3 2003 (Use several sheets if necessary) | Filing Date: AUGUST 12, 1999    | Group Art Unit: 1642           |  |
|  | Customer No. 23552              |                                |  |
| PADELLER                                       |                                 |                                |  |

|                     |                        | U  | J.S. PATENT DOCUMEN   | NTS                                  |   |                                 |                   |
|---------------------|------------------------|--|---|--------------------------------------|---|---------------------------------|-------------------|
| EXAMINER<br>INITIAL | DOCUMENT NO.           | DATE   | NAME  | CLASS                                | SUBCLASS                                    |                                 | OPRIATE           |
|                     | 5,807,706              | 09/15/1998   | CARTER ET AL.   |                                      |   |                                 |                   |
|                     | 5,821,333              | 10/13/1998   | CARTER ET AL.   |                                      |   |                                 |                   |
|                     |                        | FOR  | EICN DATENT DOCUM   | AEN/TC                               |   |                                 |                   |
| <u>,</u>            | DOCUMENT NO.           | DATE   | COUNTRY   | CLASS                                | SUBCLASS TRANSLATION                        |                                 | LATION            |
|                     | 2000,1121,1101         |  | COCIVIRI  | CLASS                                | SUBCLASS                                    | YES                             | NO                |
|                     |                        |  |   |                                      |   |                                 |                   |
|                     | ОТНЕ                   | DOCUMENTS  | [ Including Author, Title,  | Date, Pertinent I                    | Pages, Etc.)                                |                                 |                   |
|                     |                        |  | Structure and Antigen Bir ntibodies", The Journal of              |                                      |   |                                 | anti-             |
|                     |                        | A. et al., "Chara<br>7:436-440 (1993                     | cterisation of a humanized  | bispecific mono                      | clongal antibody fo                         | or cancer thera                 | py", <u>Br. J</u> |
|                     |                        | et al., "Toward are rapy, 4(5):463-                      | The Production of Bispecifi<br>470 (Oct. 1995)                    | ic Antibody Frag                     | gments for Clinical                         | Applications'                   | ', <u>J.</u>      |
|                     | Carter, P. (Aug. 199   |  | ing antibodies for imaging  | and therapy", C                      | urr. Opin. Biotechn                         | ology, 8(4):4                   | 49-454            |
|                     |                        |  | ction and Characterization (5-1412 (Dec. 1995)                    | of Bispecific Sin                    | gle-Chain Antibod                           | y Fragments"                    | , <u>Mol.</u>     |
|                     | Goddard                | Goddard et al., NCBI Genbank AF048774 (1998)             |   |                                      |   |                                 |                   |
|                     | Goddard                | Goddard et al., NCBI Genbank AF048775 (1998)             |   |                                      |   |                                 |                   |
|                     | through F              | G. et al., "Conve<br>leavy Chain Con<br>2, 269(11):7934- | rsion of an Anti-single-stranplementarity Determining 7940 (1994) | nded DNA Activ<br>Region Transpla    | ve Site to an Anti-f<br>antation", The Jour | luorescein Ac<br>nal of Biologi | tive Site         |
|                     | Gulliver,<br>on Ligano | G. et al., "Effect<br>Binding", The J                    | of Transplantation of Antil<br>ournal of Biological Chem          | oody Heavy Cha<br>histry, 269(39):24 | in Complementarit<br>1040-24045 (Sept.      | y Determinin<br>30, 1994)       | g Regions         |
|                     |                        | n, J. et al,. "Bisp<br>ng, 18(1):31-40 (                 | ecific and bifunctional sing                                      | gle chain recomb                     | inant antibodies",                          | Biomolecular                    |                   |

| EXAMINER | DATE CONSIDERED |
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

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| OIPE IN AN APPLICATION                      | Applicant: ARATHOON ET AL.      |                                |  |
| (Use several sheets if necessary)           | Filing Date: AUGUST 12, 1999    | Group Art Unit: 1642           |  |
|   | Customer No. 23552              |                                |  |

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| A TOADS  | <b>\$</b>  |  |  |
|          | Mallender, W. et al., "Comparative Properties of the Single Chain Antibody and Fv Derivatives of mAb 4-4-20",<br>The Journal of Biological Chemistry, 271(10):5338-5346 (March 8, 1996)  |  |  |
|          | Mallender, W. et al., "Construction, Expression, and Activity of a Bivalent Bispecific Single-chain Antibody",<br>The Journal of Biological Chemistry, 269(1):199-206 (Jan. 7, 1994)   |  |  |
|          | Massino et al., "Quantitative analysis of the products of IgG chain recombination in hybrid hybridomas based on affinity chromatography and radioimmunoassay", Journal of Immunological Methods, 201:57-66 (1997)                                |  |  |
|          | Merchant et al., "An efficient route to human bispecific IgG", Nature Biotechnology, 16:677-681 (July 1998)  |  |  |
|          | Muller, KM et al., "The first constant domain (C <sub>H</sub> 1 and C <sub>L</sub> ) of an antibody used as heterodimerization domain for bispecific miniantibodies", <u>FEBS Letter</u> , 422(2):259-264 (January 30, 1998)                     |  |  |
|          | Muller, KM et al., "A dimeric bispecific miniantibody combines two specificities with avidity", <u>FEBS Letter</u> , 432(1-2):45-49 (July 31, 1998)  |  |  |
|          | Pluckthun, A. et al., "New protein engineering approaches to multivalent and bispecific antibody fragments",<br>Immunotechnology, 3(2):83-105 (June 1997)  |  |  |
|          | Reddy, V. et al., "Production of Hybrids Secreting Bispecific Antibodies Recognising CEA and Doxorubicin",<br>Anticancer Research, 13:2077-2084 (1993)   |  |  |
|          | Rudikoff, S., "Single amino acid substitution altering antigen-binding specificity", <u>Immunology</u> , 79:1979-1983 (1982)   |  |  |
|          | Segal, DM et al., "Introduction: bispecific antibodies", J. Immunol. Methods, 248(1-2):1-6 (Feb. 1, 2001)  |  |  |
|          | Smith et al., "Variable Region Primary Structures of Monoclonal Anti-DNA Autoantibodies from NZB/NZW F Mice", Molecular Immunology, 27(5):463-470 (1990)   |  |  |
| "        | Tomlinson, IM et al., "The structural repertoire of the human V <sub>K</sub> domain", <u>EMBO Journal</u> , 14(18):4628-4638 (Sept. 15, 1995)  |  |  |
|          | Tomlinson, I. et al., "Methods for Generating Multivalent and Bispecific Antibody Fragments", Methods Enzymol., 326:461-479 (2000)   |  |  |
|          | Tso, JY et al., "Preparation of a Bispecific F(ab') <sub>2</sub> Targeted to the Human IL-2 Receptor", J. Hematotherapy, 4(5):389-394 (Oct. 1995)  |  |  |
|          | Vuillez, J. et al., "Two-Step Immunoscintigraphy for Non-Small-Cell Lung Cancer Staging Using a Bispecific Anti-CEA/Anti-Indium-DTPA Antibody and an Indium-111-Labeled DTPA Dimer", The Journal of Nuclear Medicine, 38(4):507-511 (April 1997) |  |  |

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